

## Performance of an intramuscular electrode during functional neuromuscular stimulation for gait training post stroke

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**Abstract**—The goal of rehabilitation for stroke patients in this research was to improve the volitional coordination of the swing phase and stance phases of gait. Functional neuromuscular stimulation (FNS) is a promising rehabilitation tool for restoring motor control. For our gait training protocols, FNS systems with surface electrodes were impractical. For the rehabilitation protocols that we defined, available implantable electrode designs did not meet desired criteria regarding fracture rate, invasiveness of placement procedures, and maintenance of position at the motor point. The criteria for the new intramuscular (IM) electrode design included minimally invasive electrode placement technique, accurate placement of electrodes, good muscle selectivity, consistency of muscle activation, good position maintenance of the electrode at the motor point, comfortable stimulus, and practical donning time for the system. A percutaneous electrode was designed for placement beneath the skin at the motor point of seven paralyzed or paretic muscles in the lower limb. A single-helical coil lead, a double-helical coil electrode, and fine wire barbs were design features that enhanced the anchoring capability of the electrode. A polypropylene core enhanced electrode durability. Implantation tools were custom-designed to enable accurate

electrode placement without incision. We studied 17 subjects with a total of 124 electrodes. With the use of IM electrodes, FNS was provided for 1,413.8 electrode months. During this time, no instances of infection occurred. The measure of electrode integrity showed a 99% electrode survival rate. Throughout the treatment protocols, 93% of the electrodes delivered a good muscle response; 7% (nine electrodes) moved from the motor point and delivered a poor muscle response during the treatment protocol. Anchoring performance was higher for electrodes implanted in muscles that moved the hip (96.0%) and ankle joints (97.45%) compared with electrodes implanted in muscles that moved the knee joint (88.5%). Ninety-seven percent of the electrodes delivered a comfortable stimulus. Three percent delivered a stimulus that was uncomfortable at therapeutic levels and therefore were not used. We achieved gains in subject impairment and disability measures. The system proved to be practical for use in both clinical and home environments.

**Key words:** *functional electrical stimulation (FES), functional neuromuscular stimulation (FNS), gait, rehabilitation technology, stroke.*

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## INTRODUCTION

Functional neuromuscular stimulation (FNS) has been considered a promising rehabilitation tool for patients with stroke (1–8). Two types of systems have

been reported: systems using surface electrodes (1–4) and systems using electrodes implanted intramuscularly (IM) (9–11). For surface systems, the obstacles to widespread use of multichannel systems included poor muscle selectivity, inconsistent muscle or nerve stimulation, pain, impractical donning time, and difficulty for patients in placing electrodes (3,4,12). To avoid these difficulties inherent in surface systems, in early studies from our laboratory, we investigated the use of an electrode that was implanted beneath the skin at the motor point of a muscle, with the lead wire exiting the skin to communicate with an externally worn stimulator (13,14). This IM electrode was constructed of a single-helix coil and a coiled lead wire (76- $\mu$ m, 10-strand, stainless steel wire, insulated with extruded FEP Teflon® (13)). This electrode functioned well in eliminating difficulties with surface systems. For the rehabilitation protocols that we are now defining, this single-helix electrode had a fracture rate and electrode movement rate greater than desired (15).

The goals of our rehabilitation protocol were to improve the volitional coordination of muscle activation and the stance and swing phases of gait. The objectives of our treatment protocols included:

- Reliable activation of seven specific lower-limb muscles.
- Activation of specific combinations of muscles and specific timing parameters for gait.
- Attainment of comfortable FNS stimuli for the patient.
- Patient use of the FNS system for 6 to 24 months.
- Home use of the system by patients with stroke.
- Sufficient ease of use of the FNS system for patient satisfaction.

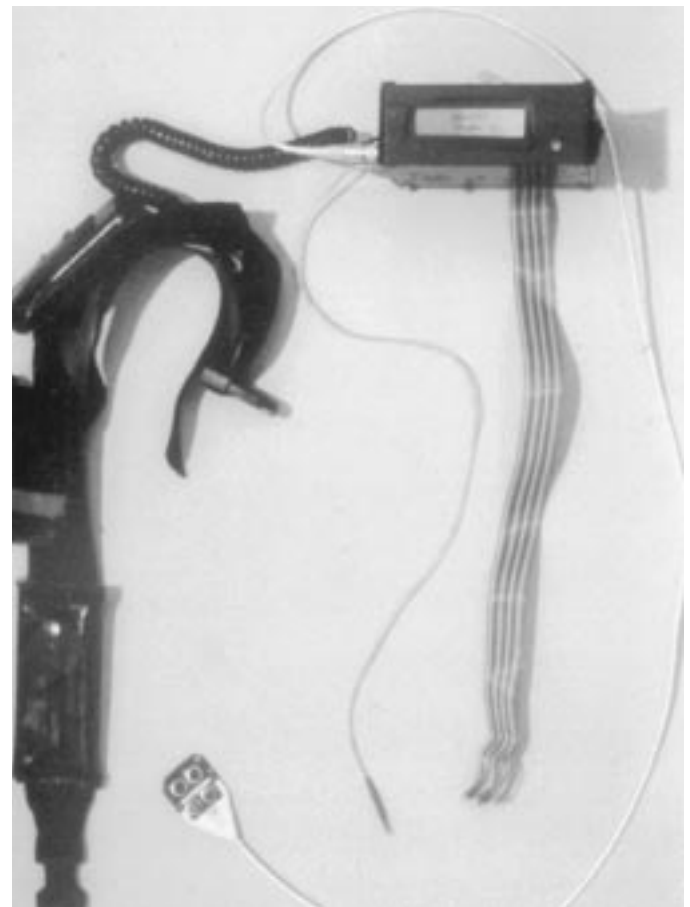
In addition, for patients with stroke, we needed an implantation procedure that would be minimally invasive and limited to one session of no more than several hours' duration. Therefore, to capitalize on the promising features of FNS rehabilitation for patients with stroke, we designed a system to meet these objectives and tested an innovative FNS-IM electrode for use specifically in lower-limb motor learning and gait training following stroke. This paper describes the design of a double-helical coil electrode, electrode performance during use with patients with stroke, and the response of patients with stroke to the use of the electrode.

## METHODS

### Materials

#### *The FNS-IM Rehabilitation System*

The electrodes were designed to function within an FNS system that included a specialized computer program for designing the patterns of stimulation (16), a portable stimulator worn on a belt, and a finger-switch controller (**Figure 1**). We used the software to create individualized FNS patterns for each subject using multiple muscles in a number of combinations and timing variations. The program allowed for editing, adding, deleting, and displaying and printing of stimulation patterns that were transferred to the subject's own stimulator. The portable stimulator was based on a V40 NEC microprocessor. The system used



**Figure 1.**

External portion of stimulation unit is shown. FNS stimulator box is shown as black rectangle in top right-hand corner. Battery belt is on far-left, and four-button finger switch is on lower-left. The ribbon cable delivers stimulus from stimulator to individual intramuscular electrodes.

24 I/O ports, 32 kB of RAM, and 2 MB of memory on an EPROM (erasable programmable read-only memory). The status of the program was displayed on a 32-character alphanumeric display. Up to 64 patterns of preprogrammed activity, such as exercises and gait training, could be selected from a menu with the use of a four-button finger switch attached to the hand, exercise bar, or cane.

#### *Electrode Performance Criteria*

The electrode performance criteria were based on the environment in which the electrode must perform and on the demands of stroke rehabilitation and gait training. The lower-limb environment of electrodes for FNS-IM is mechanically demanding because of three factors. First, the electrode lead wire traverses long distances, sometimes crossing a joint. Second, the electrode lead traverses through multiple layers of tissue, which move with respect to each other during motor tasks. Third, during muscle contractions, the electrode and lead wire are subjected to relatively large forces as the large muscles of the lower-limb contract and stretch (15).

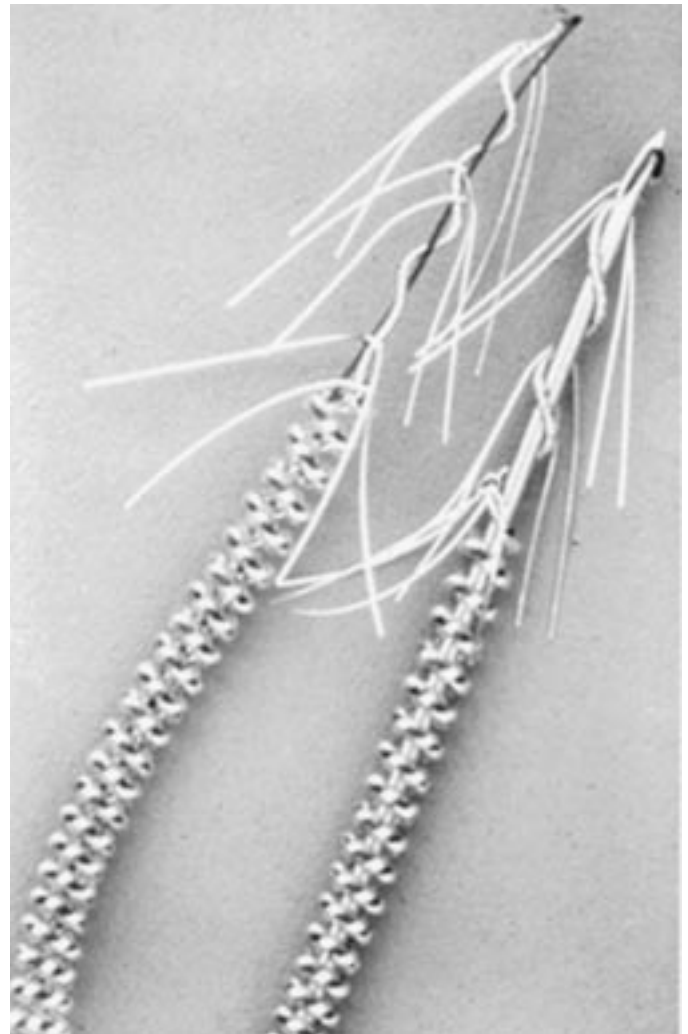
The electrode performance criteria included:

- Biocompatible material (17) that was noncorrosive and did not cause tissue damage (14,18,19).
- Low infection rate.
- Specificity of muscle activation, including deep muscles.
- Comfortable activation of muscle.
- Capability to reliably stimulate paretic or paralyzed muscle for up to 24 months.
- Long-term mechanical integrity (9,13,20,21).

In addition, the electrode design had to meet specifications required for the implantation procedure itself. The criteria for the implantation technique included implantation without surgical incision, short implantation time, short explantation time, and accuracy of placement.

#### *Electrode Design*

The electrode (**Figure 2**) had a number of features designed to provide flexibility, durability, and security of placement. First, for flexibility, the entire lead wire was wound in a single-helical coil configuration. In addition, 9 cm of the most distal portion of the lead wire were configured in a double-helical coil. Second, the entire electrode and lead wire were wound and mounted around the polypropylene core for durability. Twelve barbs were affixed to the electrode (6-mm long, 316LVM stainless steel wire)



**Figure 2.**

Two double-helical intramuscular electrodes are shown. Electrode on right is mounted on a needle in preparation for insertion at motor point. Electrode on left is shown without needle. Stainless steel wire (white) is wound around polypropylene core (black). Distal and deinsulated portion is wound around core and has single-strand wire barbs tied at intervals. Remainder of electrode is configured in a double-helical coil for enhanced flexibility. Remainder of lead wire (not shown) is configured in a single-helical coil.

for securing the electrode. Additionally, the distal end of the polypropylene core was configured with a 5-mm hook (15).

The material for the conducting lead wire was a ten-strand (strand, 48  $\mu\text{m}$  in diameter, and cable, 205  $\mu\text{m}$  in diameter) 316LVM stainless steel wire (Cooner Wire Co., Shatsworth, CA) insulated with extruded FEP Teflon® (resistance, 139  $\Omega/\text{m}$ ; with insulation 0.28 mm in diameter). We chose this stainless steel material for the lead wire because of the following characteristics: resistance

to mechanical fatigue; high strength, low electrical resistivity; high-charge ejection limit; and minimal passive tissue response (18,22–24). The Teflon® material was chosen for the insulator because of high strength and toughness (amount of energy per unit volume before fracture or failure; MPam) and good biocompatibility (10,21). The electrode lead core was polypropylene material (0.15 mm in diameter), chosen for its biocompatibility, toughness, and strength (25–29). In preparation for implantation, the electrode was mounted on a 26-gauge needle and sterilized with ethylene oxide gas.

### Implantation Procedure

Taking precautionary measures, prior to the electrode placement procedure, subjects had an EKG, lab tests (PT, PTT, BUN), and 3 days of antibiotic medication following the procedure. We performed the implantation procedure in an ambulatory care surgery setting in a surgical suite using monitored anesthesia care and conventional sterile techniques comparable to surgical hip replacement. Local anesthesia was used to minimize discomfort during the probing procedure.

A 26-gauge needle connected to a stimulator was used in an iterative procedure to locate the motor point of a paretic or paralyzed muscle. We considered an electrode position acceptable if the stimulus produced  $\geq 10^\circ$  joint movement, within a predetermined stimulus pulse-width range for each muscle (**Table 1**). To test the force elicited by muscle stimulation, we fixed the stimulus amplitude at 20 mA and the frequency at either 4 Hz (exclusively for probing) or 20 Hz (for probing and final testing). The data in **Table 1** were collected from our initial users of the FNS-IM system who had intact sensation, and the data were used during the implantation procedure to guide decision making for acceptance of a particular electrode location.

After we located a satisfactory motor point, a 17-gauge sheath was passed over the probe to a depth 1 cm proximal to the tip of the probe. A second slightly larger 15-gauge sheath was then passed over the outside of the first sheath to the same depth, in order to gently enlarge the passageway for the insertion of the electrode mounted on the 26-gauge needle. A 1-mm subcuticular incision was made to release tension at the insertion site.

We then removed the probe and the inner sheath, leaving the larger sheath in place, marking the previously identified motor point. The electrode, mounted on a 26-gauge needle, was then inserted via the 26-gauge needle through the remaining sheath to the premeasured location of the identified motor point. Then we removed

**Table 1.**

Range of pulse widths used during implantation procedure for each muscle.

Muscle	Pulse width range ( $\mu$ s)
Tibialis anterior	24–47
Peroneals	11–34
Gastrocnemius	1–10
Quadriceps	5–14
Shorthad biceps femoris	22–40
Longhead biceps femoris	16–52
Amplitude = 20 mA	
Frequency = 20 Hz	

the 26-gauge needle, leaving the electrode in place and the lead exiting the skin temporarily at the site of insertion. The barrel protecting the lead wire was removed, as was the remaining sheath.

We then subcutaneously routed the electrode lead to a final exit site on the mid anterior thigh. All electrode leads exited in the same region. Using an 18-gauge cannula passer with an internal stylet, we subcutaneously passed the lead. First, the passer was passed from the original lead exit site to the final desired exit site. Next, we fed a threading wire through the passer, tied it to the electrode lead wire, and pulled it through the passer, guiding the electrode lead to its final exit site. The cannula passer was then removed. Bacitracin was applied to the lead exit sites, and the region was covered with a Tegaderm® dressing. The electrode insertion sites were covered with a Band-Aid®.

At the end of the rehabilitation treatment protocol, we removed the electrodes by applying tension to the lead wire and pulling the lead and electrode out through the existing lead exit site. This procedure was performed under anesthesia.

### Preparation of Electrodes for FNS Rehabilitation

Two days after implantation, the electrode lead wires were crimped into a multipin connector for use with a cable attached to the stimulator. Each electrode was profiled according to its capability to produce a minimal sensation, minimal muscle contraction, the strength of the muscle contraction in response to stimulation (within subject comfort), and the maximum stimulus parameters tolerated. The range of stimulus parameters was as follows: amplitude, 4 to 20 mA; frequency, 33 Hz; and pulse width, 3 to 150  $\mu$ s. Initially, using one electrode per exercise, we created exercises for the stimulated muscles.



## Outcome Measures

### *Electrode Performance and Implantation Technique*

The implantation technique and electrode were evaluated according to a number of measures: (1) time to implant electrode; (2) reliability of electrode position maintenance during implantation, according to longitudinal measures of electrode performance during the implantation session; and (3) time to explant electrodes. First, we monitored the time required to place an acceptable electrode for each of seven muscles: tibialis anterior, peroneal, lateral gastrocnemius, quadriceps, short head of the biceps femoris, long head of the biceps femoris, and gluteus medius. Our measures included time to locate the motor point, as well as time to insert the electrode, tunnel the lead wire, and perform a final electrode test.

Second, we monitored the strength of the muscle response during the probing phase, after initial electrode placement and after passing the lead wire to the common exit site. This information indicated the reliability of the implantation protocol and the electrode in maintaining the electrode position during the use of the implantation tools and during the tunneling of the lead wire to the common exit site. We used the five-point manual muscle test grading scale accepted for clinical use (30). Third, we monitored the time required for explantation of electrodes.

### *Criteria for Electrode Performance*

Electrode performance was further assessed according to three factors: (1) mechanical performance, (2) physiological performance, and (3) subject response to

electrode. The criteria for these factors are listed in **Table 2**.

### *Mechanical Electrode Performance*

One hundred twenty-four electrodes in 17 subjects were studied. We admitted eight subjects with acute stroke into the study for rehabilitation at 3 weeks to 3 months following stroke. Nine subjects with chronic stroke were enrolled at 12 months or more following stroke (**Table 3**). We monitored the electrodes weekly to determine electrode integrity. First, on the leading edge of the stimulus waveform, the electrode impedance at the time of implantation was determined. We assumed that impedance exceeding two to three times its original value indicated an electrode with a mechanical failure or break. We then measured electrode impedance each week by applying a current-controlled train of pulses through the electrode, identical to that used for activating the muscle during treatment, and we measured the peak negative voltage. The total number of electrodes with normal and high impedance was calculated, along with the total number of electrode-months used. The standard, nonparametric Kaplan-Meier (31) survival-curve estimate was calculated for mechanical failure, accounting for varying durations of electrode use according to planned treatment protocols and indicating risk of mechanical failure at any given time. We calculated the hazard rate according to the following formula:

Hazard rate = number of failures ÷ (time from last failure × number of electrodes).

**Table 2.**

Three performance factors and criteria.

Performance factor	Criteria
<b>Mechanical performance</b>	
1. Electrode durability	1. Number of months exhibiting normal range impedance, assuming that high impedance is an indication of mechanical failure or break of lead or electrode.
2. Electrode anchoring performance	2. Number of months during which electrode maintained activation of desired muscle (loss of activation assumed caused by electrode movement).
<b>Physiological performance</b>	
1. Elicitation of muscle contraction within subject comfort level	1. Number of electrodes producing pain-free/painful sensation
2. FNS and volitional recruitment	2(a). Initial tolerated PW, max PW tolerated. (b). Number of electrodes producing a desired FNS muscle contraction beyond volitional capability.
3. FNS recruitment for motor patterning	3. Knee extensor and flexor response against gravity.
<b>Subject response</b>	
1. Body tissue tolerance	1(a). Number of infections; record of resolution. (b). Number of skin erythema instances; record of resolution.

**Table 3.**  
Subject characteristics.

Subject	Age	Gender	Months poststroke	Side of lesion
<b>Acute</b>				
1	50	M	0.9	L
2	82	M	1.7	L
3	72	M	2.0	R
4	47	F	0.8	L
5	59	F	2.9	L
6	62	M	1.9	R
7	62	M	3.0	R
8	58	M	2.7	L
<b>Chronic</b>				
1	46	M	49	L
2	60	M	13	R
3	64	M	60	R
4	75	M	73	R
5	69	M	18	L
6	69	M	16	L
7	65	F	15	R
8	74	M	25	L
9	48	M	21	L

A second measure of mechanical performance was the capability of the electrode to maintain its position over time at the desired motor point. The assumption was that loss of muscle recruitment was due to the electrode moving from the motor point. A sample of 17 subjects with a group total of 124 electrodes was monitored for the continued function over time of each electrode in terms of the muscle response that was elicited. We categorized the muscle response as “good” if it produced the isolated joint movement, which was intended at implantation, and “poor” if it did not.

#### *Physiological Electrode Performance*

The first indicator of physiological performance of the electrode was stimulus comfort. For a 17-subject sample, each of 124 electrodes was monitored throughout the treatment protocol for delivery of a comfortable stimulus. The determination of “comfortable” versus “painful” was a subjective judgment that the subject made for each electrode. If the subject identified an electrode as “painful” during use at a therapeutic level, it was no longer used and was removed.

A second indicator of the electrical performance of the electrode was the change in maximum pulse width tolerated during the treatment protocol. For an eight-subject sample, maximum tolerated pulse width for each

electrode was tested initially and after 3 months of the subject’s study participation.

A third measure of performance of the electrode was the capability to recruit muscle response sufficient to surpass the volitional performance of that muscle. An eight-subject sample with a total of 52 electrodes was monitored. We awarded a “good” electrode performance for production of a muscle response at least 0.33 of a manual muscle test grade greater than volitional capability. We assigned a “poor” performance for a muscle response lower than that criterion.

A fourth measure was the function of the electrodes for knee extension. We tested subjects for volitional capability of standing on the involved limb while volitionally maintaining the knee in neutral position (2 degrees of knee flexion), the body in neutral alignment, and 100 percent of body weight shifted to the involved limb. Subjects were categorized as unable to perform the maneuver (1) if the knee moved into hyperextension, (2) if the knee moved into hyperflexion, and (3) if upper-limb support was required to maintain neutral knee position. Subjects were then retested with the same criteria in the weight-shift maneuver with the addition of FNS activation of the quadriceps muscle. The FNS quadriceps was characterized as unable to perform the maneuver, according to the above three criteria.

A fifth measure was the function of the electrodes for knee flexion. We tested knee flexion in the standing position with the full body weight on the uninvolved side, the involved toe touching the floor behind the body, the involved hip in neutral position, and the involved knee in 30 degrees flexion. We asked subjects to flex the knee without moving other body parts. Subjects were categorized as unable to perform the maneuver (1) if the knee did not flex and (2) if the knee flexed but other body parts moved. Subjects were then retested with the same criteria for knee flexion with the addition of FNS activation of the knee flexors. FNS knee flexors were characterized as unable to perform the maneuver, according to the same two criteria.

#### *Response of Subjects to Electrode*

For 17 subjects with a total of 124 electrodes, skin and tissue integrity was monitored at each electrode lead exit site of the skin and along the lead pathway beneath the skin. We monitored three response measures: (1) infection of the electrode and lead wire during use, (2) erythema of the skin at the lead exit site, and (3) infection of the electrode and lead wire fragment after the close of

the treatment protocol. The criteria for infection caused by the electrode and lead wire were the presence of a positive bacterial culture and erythema, edema, and warmth along the lead wire beneath the skin. The criteria for an instance of erythema were redness of the skin around the lead exit site and a positive bacterial culture. The criteria for infection caused by a fragment were erythema, edema, and warmth along the pathway of the fragment and a positive bacterial culture. Following electrode removal, we contacted subjects for follow-up regarding any instance of infection, discomfort, or any other event or symptom caused by the presence of remaining fragments.

#### *FNS-IM System Use and User Satisfaction*

For 17 subjects, we monitored the manner in which the treating physical therapist was able to use the FNS-IM system for rehabilitation, including muscle strengthening, muscle endurance, coordination, gait training, walking, and stair climbing. In addition, the treating therapists evaluated each subject's independence in using the FNS-IM system for exercise and gait. Finally, we asked each subject to evaluate satisfaction with the system regarding practicality, comfort, and ease of use.

#### *Electrode Treatment Feasibility*

We treated eight subjects with acute stroke with conventional therapy plus FNS-IM. We monitored days lost from rehabilitation following electrode implantation, gains in impairment, and gains in disability over 6 months. Impairment measures included muscle strength (manual muscle testing principles (30)), the Fugl-Meyer Coordination Scale (32,33), and the Tinetti Balance and Gait Scales (34). The disability measure was the Functional Independence Measure (FIM) (35–37). The Wilcoxon rank sign test was used for pre- and posttreatment comparisons (38).

#### *Electrode Treatment Efficacy*

We monitored nine subjects with chronic stroke for gains using the intramuscular electrodes compared with gains obtained using surface electrodes and conventional therapy for 3 months before implantation of the intramuscular electrodes. Impairment measures included muscle strength (manual muscle testing principles and the Fugl-Meyer Coordination Scale). Functional changes were documented and included pain during walking, use of wheelchair, walking endurance, and number of falls.

## RESULTS

### **Electrode Performance and Implantation Technique**

#### *Time to Implant Electrodes*

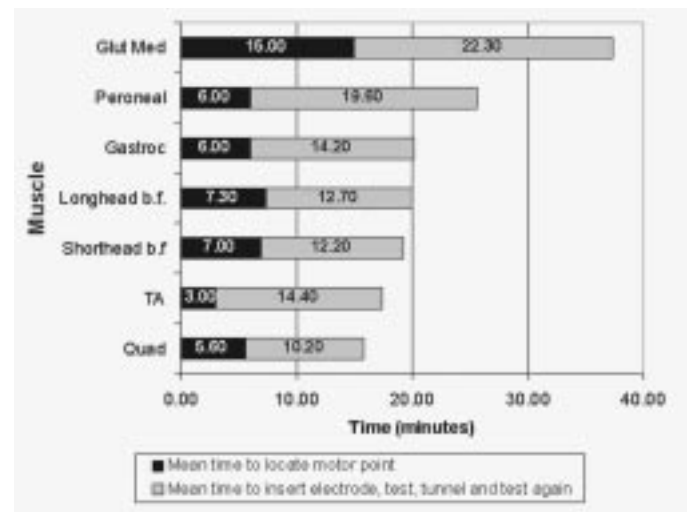
We placed up to seven electrodes during a single session, which lasted 3 hours or less. The placement of each electrode required from 15 to 37 min. **Figure 3** presents mean implant times for each muscle (total time = dark + light bar). The gluteus medius required the longest total time for implantation ( $37.3 \text{ min} \pm 17.4$ ), and the quadriceps required the shortest time ( $15.8 \text{ min} \pm 4.1$ ). With the exception of the gluteus medius, the time for the remaining six muscles ranged within 9.8 min of each other (15.8 to 25.6 min).

The dark shaded bars show the time required for each muscle to locate the motor point. For locating the motor point, the tibialis anterior required the shortest time ( $3.0 \text{ min} \pm 1.6$ ). Excluding the gluteus medius, the remaining muscles were within a range of 1.7 min of each other (5.6 to 7.3 min).

The light shaded bar shows the time required to place the electrode, test it, tunnel the lead wire, and retest. The quadriceps required the shortest time ( $10.2 \text{ min} \pm 2.2$ ). Excluding the gluteus medius, the time required for the remaining electrodes was within 9.4 min of each other (10.2 to 19.6 min).

#### *Time to Explant Electrodes*

The short head of the biceps femoris required the longest explant time ( $2.5 \pm 1.0 \text{ min}$ ). The remaining six muscles were within 1 min of each other in time required

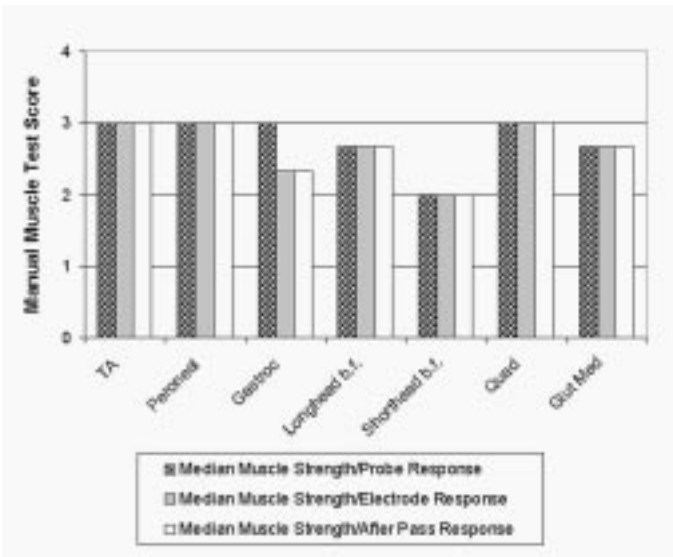


**Figure 3.** Mean implant times for each of seven muscles.

(1.0 to 2.0 min per electrode). The total explantation session required  $\leq 30$  min.

*Electrode Maintenance at Motor Point Throughout Implantation Procedure*

The three different bars for each muscle in **Figure 4** show three muscle strength measures in response to FNS activation during the implantation session, specifically (1) at initial probe (diamond patterned bar); (2) at initial electrode placement (light shaded bar); and (3) last test at implantation, after passing the lead wire (white bar). Overall, the median muscle strength in response to FNS was between grades of 2.0 (short head, biceps) and 3.0 (tibialis anterior, peroneals, and quadriceps). Between probe placement and initial electrode placement, 40 of 42 electrodes maintained a consistent muscle response to stimulation. Between initial electrode placement and final electrode test,



**Figure 4.** Median manual muscle test score at three testing times during implantation (six subjects).

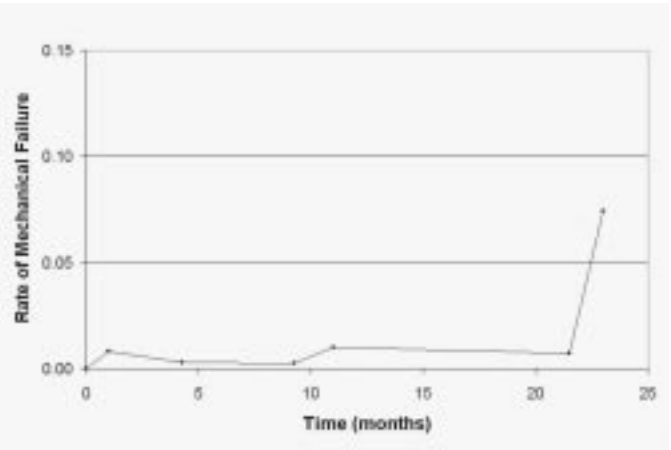
**Table 4.** Mechanical durability measures.

Subjects	A. Total number of electrodes	B. Normal impedance (No. of electrodes)	C. Abnormal impedance (No. of electrodes)	D. Total electrode months free of failure
Acute (n=8)	55	55	0	484.9
Chronic (n=9)	69	63	6	928.9
Totals	124	118	6	1,413.8

39 of 42 electrodes maintained a consistent response to stimulation.

**Electrode Performance**  
*Mechanical Performance—Durability*

**Table 4** shows that for the 17-subject sample, 124 electrodes were provided. For the acute subjects, no mechanical failures of breakage occurred (high impedance = 0, column [col.] C). For the chronic subjects, six electrodes exhibited high impedance and assumed breakage. The first subject who entered the study used five of these six failed electrodes. For the subsequent 16 subjects, only one mechanical failure occurred (high impedance). Overall, 1,413.8 total electrode-months were used, which were free of any mechanical durability failure (col. D). **Figure 5** shows the rate of mechanical failure. For the total subject group, given the six failed electrodes and the time of the failure, there was a 99.6 percent chance of electrode survival at 9 months of use, and through month 21, there was a continuation of a  $\geq 99$ -percent chance of electrode survival. By month 23 (last data point), only nine electrodes were in use.



**Figure 5.** Instantaneous rate of mechanical failure.



### Mechanical Performance—Anchoring Capability

**Table 5** provides information regarding the effectiveness of the mechanical flexibility of the electrode and lead wire, along with the capability of the electrode barbs to maintain the electrode at the desired motor point over time during the treatment protocol. One hundred fifteen electrodes provided good muscle response throughout the 6- to 24-month treatment protocols; nine electrodes provided a poor muscle response during the treatment protocol. **Figure 6** illustrates a relatively higher rate of mechanical anchoring performance for the hip (96.0 percent) and ankle (97.45 percent) muscle electrodes when compared to electrodes for knee muscles (88.5 percent).

### Physiological Performance

For subjects with both chronic and acute stroke, **Table 6** shows the number of electrodes producing a comfortable stimulus or a painful stimulus. Of the 124 electrodes, 121 (97.5 percent) produced a comfortable stimulus (col. C) and 3 produced a painful stimulus. An electrode that was identified by the subject as painful

(within the minimally useful stimulus level) was no longer used and removed immediately or at the end of the protocol.

For all muscles, the electrodes functioned positively over time, in that the magnitude of the comfortable pulse width increased over time (**Table 7**, col. C compared with col. B; current was held constant). For all seven muscles studied, the maximum pulse width tolerated during treatment was obtained an average of 3 months after initiation of treatment. It was an advantage for the subject to tolerate a higher pulse width, because we observed a greater percent of muscle recruitment at higher pulse widths.

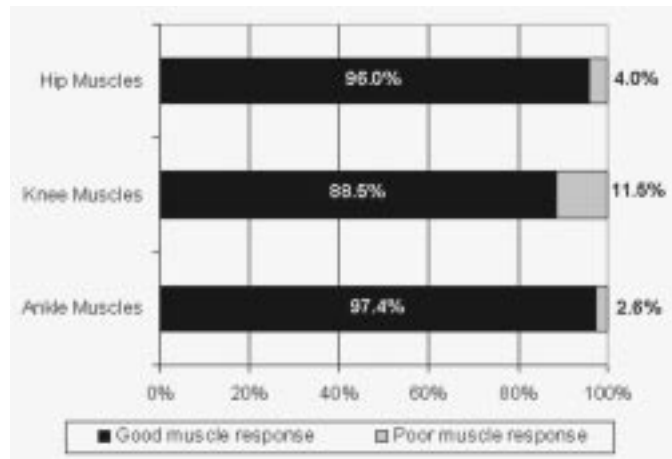
**Table 8** presents information for 12 subjects who were initially unable to volitionally support body weight with the quadriceps muscle (col. A). Their body weight ranged from 110 to 250 lb, with a mean of 170,  $\pm 20$  lb. For these 12 subjects, the FNS-driven quadriceps could support body weight (col. B). Under the assumption that the shank is 15 percent of body weight, the FNS-driven quadriceps could provide enough torque to support or assist in the support of an average of 144.5 lb (total body weight—supporting shank, col. C).

**Table 9** presents information for nine subjects who were unable to volitionally flex the knee against gravity. With FNS-driven knee flexion, all nine subjects were able to flex the knee against gravity (col. B). Under the assumption that the shank is 15 percent of body weight, the FNS knee flexors could produce enough torque to flex the shank (25.5 lb) at least 20 degrees against gravity.

### Subject Response to Electrode

**Table 10** provides information regarding instances of infection and instances of skin exit-site erythema for 124 electrodes during 1,413.8 electrode-months of use. There were no instances of infection of the electrode and lead wire (**Table 10**, col. C).

There were 14 instances of erythema at the skin exit site (col. D). For these 14 instances, the culture swabs obtained at the skin exit site grew bacteria that are com-



**Figure 6.** Mechanical flexibility and anchoring performance throughout treatment protocol.

**Table 5.** Mechanical durability measures.

Subjects	A.	B.	C.
	Number of electrodes	Good muscle response throughout treatment protocol	Poor muscle response throughout protocol
Chronic (n=9)	69	64	5
Acute (n=8)	55	51	4
Totals	124	115	9

mon skin flora, with the exception of one subject showing the presence of *Pseudomonas*. Because the erythematous area could have become an infection, the patients were treated prophylactically with oral or topical antibiotic medication, with resolution of the symptoms within 3 days for all 14 instances of erythema. One of these electrodes was removed before completion of the treatment protocol. Individual differences explain the etiology of

some of the instances of skin erythema. One subject had 4 of the 14 total instances of erythema. We determined that his caregiver was scrubbing the skin around the electrode sites and possibly irritating the tissue, counter to site-care instructions; after the caregiver was reinstructed in site care, the subject experienced no additional instances of erythema. A second subject had 6 of the 14 total instances of erythema. This particular subject had

**Table 6.**

Number of electrodes producing a comfortable stimulus.

Subjects	A. Number of electrodes	B. Number of electrodes producing a painful sensation	C. Number of electrodes producing a comfortable sensation
Chronic (n=9)	69	3	66
Acute (n=8)	55	0	55
Totals	124	3	121

**Table 7.**

Electrical performance of electrodes during treatment (n=8 subjects).

Muscle	A. Number of electrodes	B. Initially tolerated maximum pulse width (mean in $\mu$ s)	C. Final tolerated maximum pulse width (mean in $\mu$ s)
TA	8	51.88 $\pm$ 48.38	94.63 $\pm$ 68.78
Peroneal	8	52.13 $\pm$ 28.82	91.75 $\pm$ 46.78
Gastroc	7	59.43 $\pm$ 37.74	77.43 $\pm$ 43.73
Quad	7	55.29 $\pm$ 41.74	91.71 $\pm$ 75.27
Shorthead biceps femoris	7	51.71 $\pm$ 39.56	107.57 $\pm$ 78.14
Longhead biceps femoris	8	34.25 $\pm$ 18.18	59.63 $\pm$ 25.04
Glut Med	5	47.40 $\pm$ 30.34	76.60 $\pm$ 32.28
Sartorius	1	11.00	101.00

Amplitude = 20 mA  
Frequency = 30 Hz

**Table 8.**

Quadriceps capability to support body weight.

A. Volitional quadriceps unable to support body weight	B. FNS quadriceps able to support body weight	C. Mean body weight supported by FNS+volitional quadriceps
12 subjects	12 subjects	144.5 lb

**Table 9.**

Flexors capability to support shank weight.

A. Volitional flexors unable to flex knee against gravity	B. FNS flexors able to flex knee against gravity	C. Mean leg weight supported by FNS+volitional flexors
9 subjects	9 subjects	25.5 lb

obvious difficulties with personal hygiene and inconsistent performance of activities of daily living. Because of individual differences, the number of erythema instances did not uniformly increase with the number of electrodes per subject. Similarly, the number of erythema instances did not uniformly increase with the number of electrode-months of use per subject. For example, a subject with 220 electrode-months of use (the second longest record of use) had only one instance of erythema; conversely, one subject had four instances of erythema by 60 electrode-months of use. None of the 124 electrodes had an instance of infection.

At the close of the FNS-IM treatment protocol when the electrodes were removed, a portion of fine wire fragment for 90 electrodes remained in the body (Table 11, col. A). There were no infections (col. C) for a total of 4,292 fragment-months, and there was no instance of any other symptom or event related to the remaining fragments (col. D).

#### *FNS-IM User Satisfaction and System Use*

All subjects responded positively to the use of the system, reporting that the system was practical, comfortable, and easy to use. Following electrode implantation, the subjects were monitored and released within 4 hours. Following implantation, patients reported either no pain at all or thigh discomfort for 24 hours (except for one patient who reported discomfort for 4 days). Immediately following implantation, all subjects had the same ambu-

latory status as before the procedure. The subjects with acute stroke missed only 1 day of conventional rehabilitation for the implantation procedure (39).

#### *FNS-IM Feasibility*

The FNS-IM system was practical to use. All subjects learned to don the system and use the stimulator within 1 to 3 weeks and then used the stimulator for an individualized home exercise program. They reported no discomfort during the FNS-IM exercise and gait training sessions. According to the patient satisfaction survey, subjects were satisfied with the technology and felt that any inconveniences were inconsequential (39). According to therapist evaluation results, the FNS-IM system was useful during rehabilitation for exercise and gait training in muscle strengthening (100 percent of subjects), muscle endurance (88 percent of subjects), coordination training (88 percent), gait training (88 percent), and stair climbing (59 percent). Subjects with acute stroke significantly improved with gains in FIM score, muscle strength, Fugl-Meyer Coordination Scale, and Tinetti Balance and Gait Scales ( $p \leq 0.029$ ).

#### *Electrode Treatment Efficacy*

Chronic subjects (>1 year post stroke) showed significant gains in coordination, strength, endurance, and gait pattern beyond gains obtained during conventional rehabilitation ( $p = 0.01$ ) (7,8). Functional changes included a

**Table 10.**  
Physiological factors of electrode performance.

	A.	B.	C.	D.	E.
Subjects	Total No. of electrodes implanted	Total No. of electrode months	Total No. of infections	Instance of skin site erythema	Total No. of electrodes removed following erythema instance
Chronic	69	928.9	0	14	1
Acute	655	484.9	0	0	0
Total	124	1,413.8	0	14	1

**Table 11.**  
Biocompatibility of electrode fragments.

	A.	B.	C.	D.
Subjects	Total No. of fragments in body	Total No. of fragment months	No. of infections	No. of other symptoms
Chronic	51	3,667.6	0	0
Acute	39	624.7	0	0
Total	90	4,292.3	0	0

reduction in number of falls and improved mobility and participation in social and leisure activity (6,7).

## DISCUSSION

### Electrode Performance and Implantation Technique

The electrode design, along with the custom designed implantation tools, allowed the placement of up to eight electrodes within a 3-hour session, with minimal invasiveness, minimal discomfort, and without disruption of the subject's mobility level and normal activities. For patients with stroke, these are important outcomes, given the considerable disability and handicap with which they must contend. Because the implantation procedure required less than a day, the FNS-IM treatment was feasible within a conventional rehabilitation setting. The electrode implantation tools, technique, and electrode, together resulted in successful placement of electrodes at the motor point of muscles and maintenance of the electrode in position throughout the procedure.

### Electrode Performance

#### *Durability, Flexibility, and Anchoring Capability*

When one considers the low rate of breakage, the electrode design was successful in functioning within an environment that required long lead wires, large muscle forces, tissue shear forces, joint crossings, and large excursions of movement. The design features for anchoring the electrode also functioned well. The assumption was that if the electrode maintained its position over time during the muscle contractions required for exercise and gait, then the double- and single-helical coil construction of the electrode and lead wire, respectively, was flexible enough to withstand the excursions of muscle and joint movement without dislodging the electrode from the initial motor point. In addition, the assumption, in that case, was that the fine wire barbs affixed to the electrode would function adequately to help maintain the electrode position at the desired motor point. Ninety-three percent of the electrodes maintained their position sufficiently to result in a good muscle response throughout the treatment protocol. Only nine electrodes did not maintain their position. A number of reasons could explain why an electrode could move from its original position at the motor point, including joint excursion, muscle contraction, and passive stretching of tissue. For the patients with stroke in this study,

almost all lower-limb muscles were initially below a volitional strength grade of 3. As the muscles strengthened, the configuration of the muscle changed. This also could have resulted in a change in position of the electrode relative to the motor point. A higher percentage of anchoring failures occurred in the knee muscles compared to hip and ankle muscles. This finding suggests that muscles with both greater length and mass were more at risk for altering the relationship between the electrode and the motor point.

#### *Physiological Performance*

The electrodes delivered a stimulus that was considered comfortable by the subjects. Over time, the electrode could deliver a higher stimulus within comfort. The comfortable stimulus resulted in muscle contractions sufficient to support body weight (quadriceps, **Table 10**), lift a limb segment against gravity (knee flexors, **Table 10**), produce gains in volitional coordination and strength (7,8), and improve gait pattern (6,7).

#### *Subject Response to Electrodes*

With the use of a lead wire that exits the body, there is a risk of infection. Our subjects had no infections during 1,413.8 electrode-months of use. Sixty-five percent of the subjects had no instance of skin erythema. Four subjects had one instance of skin erythema, and two subjects had four and six instances, respectively. The two latter subjects together had 72 percent of the instances of skin erythema, for reasons that were known (scrubbing and irritating the skin around the lead wires and uncleanness, respectively). Four subjects each had one instance of skin erythema. These instances resolved within 3 days of oral or topical antibiotic, and the electrodes continued to function well throughout the remainder of the treatment protocol. When subjects were queried via written questionnaire at the end of the study, they reported that any inconveniences were inconsequential.

In follow-up surveys, subjects reported that the electrode fragments remaining in the body for up to 10 years did not cause symptoms or inconvenience of any kind. A possible reason why patients experienced no problems is that the materials used to construct the electrode have been tested for biocompatibility and are used for many purposes including sutures, joint replacements, bone plates, bone screws, and arterial grafts (40). Another reason could be that the material



remaining in the body, after the FNS-IM treatment, is less than that which is permanently implanted for other purposes, such as joint replacement.

## CONCLUSIONS

The electrodes fulfilled the performance criteria, with a good mechanical performance, a practical physiological performance, and a safe and acceptable subject response. The risks of the FNS-IM system do not appear prohibitive. Given the usefulness of the FNS-IM system during rehabilitation and the gains experienced by patients with stroke, the potential for the FNS-IM system for exercise and gait training deserves further study.

## REFERENCES

- Malezic M, Bogataj U, Gros N, Decman I, Vrtacnik P, Klajic M, Acimovic-Janezic R. Application of a programmable dual-channel adaptive electrical stimulation system for the control and analysis of gait. *J Rehabil Res Dev* 1992;29:41–53.
- Malezic M, Hesse S, Schewe H, Mauritz KH. Restoration of standing, weight-shifting, and gait by multichannel electrical stimulation in hemiparetic patients. *Int J Rehabil Res* 1994; 17:169–79.
- Bogataj U, Gros N, Malezic M, Kelij B, Klajic M, Acimovic-Janezic R. Restoration of gait during two of three weeks of therapy with multichannel electrical stimulation. *Phys Ther* 1989; 69(5):319–26.
- Bogataj U, Gros N, Klajic M, Acimovic-Janezic R, Malezic M. The rehabilitation of gait in patients with hemiplegia: a comparison between conventional therapy and multichannel functional electrical stimulation therapy. *Phys Ther* 1995;75:38–52.
- Chae J, Hart R. Comparison of discomfort associated with surface and percutaneous intramuscular electrical stimulation for persons with chronic hemiplegia. *Am J Phys Med Rehabil* 1998; 77(6):516–22.
- Daly JJ, Kobetic R, Marsolais EB. Electrically induced gait changes post stroke, using an FNS system with intramuscular electrodes and multiple channels. *J Neurol Rehabil* 1993;7:17–25.
- Daly JJ, Ruff RL. Electrically induced recovery of volitional gait components for older stroke patients. *Am J Phys Med Rehabil* 2000;79(4):349–60.
- Daly JJ, Ruff RL. Response of prolonged flaccid paralysis to rehabilitation techniques. *Disabil Rehabil* 2000 Sep;22(12):565–73.
- Handa Y, Noshimiya N, Iguchi Y, Oda T. Development of a percutaneous intramuscular electrode for multichannel FES system. *IEEE Trans Biomed Eng* 1989;36(7):705.
- Waters, RL, McNeal DR, Faloon W, Clifford B. Functional electrical stimulation of the peroneal nerve for hemiplegia. *J Bone Joint Surg* 1985 June;67-A(5):792–3.
- Strojnik P, Acimovic-Janezic R, Vavken V, Soimic R, Stanic U. Treatment of drop foot using an implantable peroneal underknee stimulator. *Scand J Rehabil Med* 1987;19:37–43.
- Stanic R, Acimovic-Janezic R, Gros N, Trnkoczy V, Bajd T, Klajic M. Multichannel electrical stimulation for correction of hemiplegic gait. *Scand J Rehabil Med* 1978;10:15–92.
- Marsolais EB, Kobetic R. Implantation techniques and experience with percutaneous intramuscular electrodes in the lower extremities. *J Rehabil Res Dev* 1986;23(3):1–8.
- Mortimer JT, Kaufman D, Roessman U. Intramuscular stimulation: Tissue damage. *Ann Biomed Eng* 1980;8:235–44.
- Scheiner A, Polando G, Marsolais EB. Design and clinical application of double helix electrode for functional electrical stimulation. *IEEE Trans Biomed Eng* 1994;41(5):425–31.
- Borges G, Ferguson K, Kobetic R. Development and operation of portable and laboratory electrical stimulation systems for walking in paraplegic subjects. *IEEE Trans Biomed Eng* 1989; 36(7):798–801.
- Caldwell C, Reswick JB. A percutaneous wire electrode for chronic research use. *IEEE Trans Biomed Eng* 1975;22(5):429–32.
- Agnew WF, McCreery DB. Neural prostheses—Fundamental studies. Englewood Cliffs, NJ: Prentice Hall, Inc.; 1990. p. 25–7.
- Scheiner A, Mortimer JT, Roessman U. Imbalanced biphasic electrical stimulation: muscle tissue damage. *Ann Biomed Eng* 1990;18:407–29.
- Bibel GB, Michael M, Utter J. Artificial nerves designed with ultrafine wire. *Wire J Int* 1987 Dec;32–9.
- Scheiner A, Mortimer JT, Kicher T. A study of the fatigue properties of small diameter wires used in intramuscular electrodes. *J Biomed Mater Res* 1991;25:589–608.
- Cory JM. Tissue response and corrosion studies of the Peterson-type intramuscular electrode MS thesis. Cleveland, OH: Case Western Reserve Univ.; 1990 August.
- Laing PG, Ferguson AB, Hodge E. Tissue reaction in rabbit muscle exposure to metallic implants. *J Biomed Mater Res* 1967; 1:135–49.
- Sutow EJ, Pollack SR. The biocompatibility of certain stainless steels. In: Williams DF, editor. *The biocompatibility of clinical implant materials*. Boca Raton, FL: CRC Press, Inc.; 1981. p. 45–98.
- Clayman HM. Polypropylene. *Ophthalmology* 1981; 88(9):959–64.
- Hastings GW. Biocompatibility of polyethylenes and polypropylenes. In: Williams DF, editor. *The biocompatibility of clinical implant materials*. Boca Raton (FL): CRC Press, Inc.; 1981. p. 43–58.
- Kusy PS, Whaley JQ. Influence of the suture diameter on the tensile strength of polypropylene monofilaments and its relationship to the USP specification. *J Biomed Mater Res* 1984;18:781–7.
- Salthouse TN. Biocompatibility of sutures. In: Williams DF, editor. *Biocompatibility in clinical practice*. Boca Raton (FL): CRC Press; 1982. p. 11–3.
- Von Fraunhofer JA, Storey RS, Stone IK, Masterson BJ. Tensile strength of suture materials. *J Biomed Mater Res* 1985;19:595–600.
- Kendall FP, McCreary EK. *Muscle: testing and function*. 3d ed. Baltimore, MD: Williams and Wilkins; 1983.
- Selvin, S. *Modern applied biostatistical methods using S-plus*. New York (NY): Oxford Press; 1998. p. 428–33.
- Fugl-Meyer AR, Jaasko L, Layman I, Olsson S, Stegling S. Post stroke hemiplegic patient. *Scand J Rehabil Med* 1975;2:13–31.

33. Fugl-Meyer AR. The effect of rehabilitation in hemiplegia as reflected in relation between motor recovery and ADL function. *Proceedings of the International Rehabilitation Association*; 1976; Mexico City; 1976. p. 683.
34. Tinetti ME. Performance-oriented assessment of mobility problems in elderly patients. *JAGS* 1986;38:119–26.
35. Linacre J, Heinemann A, Wright B, Granger C, Hamilton B. The structure and stability of the functional independence measure. *Arch Phys Med Rehabil* 1994;75:127–32.
36. Dodds T, Martin D, Stolov W, Deyo R. A validation of the functional independence measure and its performance among rehabilitation patients. *Arch Phys Med Rehabil* 1993;74:531–6.
37. Heinemann A, Linacre J, Wright B, Hamilton B, Granger C. Relationship between impairment and physical disability as measures by the functional independence measure. *Arch Phys Med Rehabil* 1993;74:566–73.
38. Portney LG, Watkins MP. *Foundations of clinical research: applications to practice*. Norwalk (CT): Appleton and Lange; 1993.
39. Daly JJ, Ruff RL, Kollar K, Strasshofer B, Marsolais EB, Dobos L. Feasibility of gait training for acute stroke patients using FNS with implanted electrodes. *J Neurol Sci.* 2000 Oct 1;179(S 1–2):103–7.
40. Park JB, Lakes RS. *Biomaterials: an introduction*. 2d ed. New York, NY: Plenum Press; 1992.

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